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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,409	04/23/2008	Hans Gronlund	1768-139	4548

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EXAMINER	
ROONEY, NORA MAUREEN	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
09/09/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)
	10/554,409	GRONLUND ET AL.
	Examiner	**Art Unit**
	NORA ROONEY	1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 August 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: ____.
   Claim(s) objected to: *22*.
   Claim(s) rejected: *22,28,33,37,38 and 42-47*.
   Claim(s) withdrawn from consideration: *34-36,39 and 40*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Nora M Rooney/
Primary Examiner, Art Unit 1644

Continuation of 3. NOTE:

Claims 22, 28, 33, 37-38 and 42-47 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amendments and arguments filed on 08/01/2011, if entered, would clarify the mutational strategy and the response addresses the issues in section C of the rejection mailed on 08/01/2011. However, the claims still do read on any variant since Applicant did not limit the claims to 'consisting of' language. The 'variants' may comprise any number of additional amino acid changes in addition to the ones listed. Furthermore, the comprising language makes it possible to add any number of additional amino acids on the N- and/or C-terminus of the fusion protein, as evidenced by claims 42-45. Furthermore, SEQ ID NO:4 contains no mutations listed in the mutational strategy of claim 22 and does have the insertion of a cysteine between amino acids 43 and 44 of SEQ ID NO:1.

Claims 22, 28, 33, 37-38 and 42-47 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: the polypeptides of SEQ ID NO: 1, 2, 3 and fusions thereof (including SEQ ID NO:4) and compositions and kits thereof, does not reasonably provide enablement for: the polypeptide variants recited in claim 22. The terms 'variant,' 'comprising ' and 'having' are open language. As written, the claims encompass an enormous number of undisclosed polypeptide variants that may include sequence that is unrelated to the polypeptides of SEQ ID NO:1 and 2, as evidenced by claims 42-45. Claim 22 recites mutations to SEQ ID NOs 1 and 2. However, as recited, the claims still read on polypeptide variants having any number of mutations in addition to the ones listed in claim 22. It is again noted that SEQ ID NO:4 contains an additional amino acid and none of the recited mutations. Contrary to Applicant's assertion, there is no limiting definition of variants in the specifiation and the claims do encompass variants having any number of additional mutations within SEQ ID NO's 1-3. In order to perform as a pharmaceutical the composition must have pharmaceutical use. The ability to be injected or formulated with a carrier is not a pharmaceutical use. The claims must be directed to a limited genus of fusion proteins with pharmaceutical use as disclosed in the specification. Applicant's arguments regarding vaccines, proteins and antibodies for pharmaceutical use has no bearing on this rejection which is limited to the claimed fusion proteins and the pharmaceutical use thereof. See MPEP 2164.01(c)

Claims 22, 28, 33, 37-38 and 42-47 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms 'variant,' 'comprising' and 'having' are open language. As written, the claims encompass an enormous number of undisclosed polypeptide variants that may include sequence that is unrelated to the polypeptides of SEQ ID NO:1 and 2, as evidenced by claims 42-45. Claim 22 recites mutations to SEQ ID NOs 1 and 2. However, as recited, the claims still read on polypeptide variants having any number of mutations in addition to the ones listed in claim 22. It is again noted that SEQ ID NO:4 contains an additional amino acid and none of the recited mutations. Contrary to Applicant's assertion, there is no limiting definitition of variants in the specification and the claims do encompass variants having any number of additional mutations within SEQ ID NO's 1-3.

Claims 22 and 37-38 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,048,962 (PTO-892; Reference A). U.S. Patent 6,048,962 teaches the Fel d 1 allergen comprising chain 1 of reference SEQ ID NO:2 (comprising instant SEQ ID NO:1) and chain 2 of reference SEQ ID NO:6 (comprising SEQ ID NO:2) covalently bonded and a kit thereof with instructions for use. (In particular, claims 1-19, paragraph 83, whole document). The reference teaches that the covalent bonding of instant SEQ ID NOs 1 and 2 may be by the construction of gene chimeras, where chains 1 and 2, or parts thereof, may be linked to form a single contiguous chain where all or a portion of chain 1 may be linked with all or a portion of chain 2 cDNA and the resulting chimera may be produced as a recombinant hybrid (In particular, column 16, lines 56-65).